K070280
Exhibit 3

Special 510(k) Notification	getemed
CardioDay®	Project ID: 0505S1
Executive - Summary	Section 16-0001-Rev B

510(k) - Summary

Name and address of the manufacturer and sponsor of the 510(k) submission:	getemed Medizin- und Informationstechnik AG Oderstr. 77 14513 Teltow Germany Tel.: +49 3328 – 3942-0 Fax: +49 3328 – 3942-99
Official contact person for all correspondence:	Dr. Bert Schadow Regulatory Affairs Manager E-mail: schadow@getemed.de
Manufacturing Facility:	getemed Medizin- und Informationstechnik AG Oderstr. 77 14513 Teltow Germany
Date of Preparation:	2006-12-19
Device Name / Trade Name:	CardioDay®
Generic name of the device:	Holter ECG
Classification of new device:	Class II
Classification Panel:	Computer, Diagnostic, Programmable
Product Code and:	DQK
CFR Regulation Number:	21 CFR 870.1425
Legally Marketed Devices:	CardioDay® (**K051471**, getemed AG)

Description of Device:

CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values in graphical form. The physician will be able to review, edit, and print the data collected.

Comparison of Device Technological Characteristics to Predicate Device:

Specifications	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Type	IBM PC AT compatible	IBM PC AT compatible
CPU	Pentium III, 500MHz or greater	Pentium III, 500MHz or greater
RAM	128 Mbytes minimum, 256 Mbytes minimum for XP	256 Mbytes minimum
Free hard disk space	5 GB minimum 20 GB for 12-lead recordings	5 GB minimum 20 GB for 12-lead recordings
Display	17" CRT or 15" TFT, 1024 x 768 pixel (XGA), 256 colors	17" CRT or 15" TFT, 1024 x 768 pixel (XGA), 256 colors
Disc drive / floppy drive	Not required	Not required

Specifications	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
CD-ROM drive	For installation only. Needs to be replaced by a CD-ROM writer or DVD writer if archive option implemented	For installation only. Needs to be replaced by a CD-ROM writer or DVD writer if archive option implemented
Operating system	Windows 98 SE, NT (SP6a), 2000 or XP	Windows 2000 or XP (SP2)
Ports	1 parallel port sufficient; if USB devices used for printing, software key or card reader, then corresponding USB ports required	1 parallel port sufficient; if USB devices used for printing, software key, card reader, Bluetooth-Dongle, or connection for Holter recorder CardioMem® then corresponding USB ports required
Printer	Printer as any Windows™ compatible, 300 dpi	Printer as any Windows™ compatible, 300 dpi
Keyboard	Standard device	Standard device
Mouse	Standard, 2 or 3-button device	Standard, 2 or 3-button device
Installation media	(1) CD	(1) CD
Further periphery	CompactFlash (Type I) memory card reader	CompactFlash (Type I) memory card reader

Comparison of Software Characteristics:

Patient Screen	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Patient Identification Number	Yes	Yes
Patient Name, Address, Telephone	Yes	Yes
Patient Personal Data (Age, Gender, Date of Birth, etc.)	Yes	Yes
Medication	Yes	Yes
Indication	Yes	Yes
Physician's Name	Yes	Yes
Date of Recording	Yes	Yes

Analysis Options	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Analysis Duration	Yes	Yes
Primary Channel Selection	Yes	Yes
Sensitivity / Signal Quality	Yes	Yes
Tachycardia Threshold [bpm]	Yes	Yes
Bradycardia Threshold [bpm]	Yes	Yes
Pause Duration [ms]	Yes	Yes
SV Prematurity [%]	Yes	Yes
V Prematurity [%]	Yes	Yes
R on T [ms]	Yes	Yes
Pacemaker Type	Yes	Yes
Minimum Pulse Rate [bpm]	Yes	Yes
Maximum Pulse Rate [bpm]	Yes	Yes

Analysis Options	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Superimposition / QuickScan	Yes	Yes
12-Lead ECG Module	Yes	Yes
Holter Data Transfer	Yes	Yes

Events Detected	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
VES / PVC	Yes	Yes
SVES / SVE	Yes	Yes
Couplet	Yes	Yes
Triplet	Yes	Yes
VTACH / VE Tachycardia	Yes	Yes
Bigeminy	Yes	Yes
R on T	Yes	Yes
ST-Analysis	Yes	Yes
SVTACH / SVE Tachycardia	Yes	Yes
Arrhythmia / N-N Delay	Yes	Yes
Bradycardia	Yes	Yes
Burst / VE Run (4 beats)	Yes	Yes
V. STIM / V. Paced	Yes	Yes
A. STIM / A. Paced	Yes	Yes
AV. STIM / AV Paced	Yes	Yes
Undersense / Sense Failure	Yes	Yes
Exitblock / Capture Failure	Yes	Yes
Oversense / Inhibition	Yes	Yes
Pause / R-R Pause / N-N Pause	Yes	Yes
Event Marker	Yes	Yes
HR Stripes	Yes	Yes
Artifact	Yes	Yes
Normal	Yes	Yes

Functionality Available	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The comparison between the legally marketed device and the NEW DEVICE is based on their functions only and not on their names.		
Start	Yes	Yes
Read Tape	Yes	Yes
Read Digital Recorder	Yes	Yes
Import	Yes	Yes
Analyze New	Yes	Yes
Open	Yes	Yes
Edit Patient Data	Yes	Yes
Print Preview	Yes	Yes
Print	Yes	Yes
Close Recording	Yes	Yes
Close	Yes	Yes

Functionality Available	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Delete Recording	Yes	Yes
Archive	Yes	Yes
Diagnosis	Yes	Yes
View ECG	Yes	Yes
View ECG Online via OptoLink Cable	Yes	Yes
View ECG Online via USB Cable	No	Yes
View ECG Online via Bluetooth Data Transfer	No	Yes
Print Preview	Yes	Yes
Screen Scale Calibration	Yes	Yes
Screen: Color Setup	Yes	Yes
FFT Setup	Yes	Yes
Report Setup	Yes	Yes
Classes Display	Yes	Yes
PM Events Display	Yes	Yes
Events Display	Yes	Yes
HR Min./Max. Display	Yes	Yes
Statistics Display	Yes	Yes
Diagnosis Display	Yes	Yes
Overview Display	Yes	Yes
Context sensitive Help	Yes	Yes
Keyboard Shortcuts Help	Yes	Yes
Menu Entries Help	Yes	Yes
Help: About	Yes	Yes
Help: Version	Yes	Yes

Icons/Buttons Available	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and form of the icons / buttons, however, are different. It might even take more than one click to initiate a given action.		
Start: Read Digital Recorder	Yes	Yes
Start: Read Tape Recorder	Yes	Yes
Start: Open Existing Record	Yes	Yes
Digital Recorder	Yes	Yes
Tape Recorder	Yes	Yes
Open: List of Patients	Yes	Yes
Print	Yes	Yes
Rhythm Analysis	Yes	Yes
Print Preview on Screen	Yes	Yes

Options Available	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The name of those options may vary.		
Classes	Yes	Yes
Events	Yes	Yes
Heart Rate Min/Max	Yes	Yes
Average Heart Rate	Yes	Yes
Statistics: FFT Analysis	Yes	Yes
Statistics: ST Diagrams	Yes	Yes
Report	Yes	Yes
Overview	Yes	Yes
Heart Variability: RR Delay	Yes	Yes
Heart Rate Variability: RR FFT	Yes	Yes
Heart Rate Variability: 24h RR FFT	Yes	Yes
Heart Rate Variability: RR Histograms	Yes	Yes

Graphics & Displays Available	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and appearance of those displays may vary.		
Basis Sampling Rate for Graphical Displays	8 ms	4 ms
Classified Beats Grouped into Morphology Bins	Yes	Yes
Zoomed Version of Selected Beat	Yes	Yes
Context of Selected Beat	Yes	Yes
Events	Yes	Yes
Heart Rate Trend in Recording Period	Yes	Yes
Average RR Interval	Yes	Yes
Y-T Distribution	Yes	Yes
RR > 50ms Distribution	Yes	Yes
FFT Analysis	Yes	Yes
ST Diagrams	Yes	Yes
Overview 2 channels at Different Scaling Factors	Yes	Yes
Indicator for Atrial Fibrillation	No	Yes

Printout Options	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The following comparison between the legally marketed device and the NEW DEVICE is based on their functionality only. The commands to generate a given printout as well as its appearance do vary.		
Full Disclosure 2 Channels, 1 h/Page	Yes	Yes
Full Disclosure 2 Channels, 15 min./Page	Yes	Yes
Full Disclosure 2 Channels, 30 min./Page	Yes	Yes
Marked Events: 8 Events/Page	Yes	Yes

Printout Options	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
Marked Events: 32 Events/Page	Yes	Yes
Marked Events: Analysis Channel 25 mm/s	Yes	Yes
Marked Events: Analysis Channel 2.5 min + 25mm/s	Yes	Yes
Selected Channels 25 mm/s	Yes	Yes
Selected Channels 1 min. + 25 mm/s	Yes	Yes
Selected Channels 2.5 min. + 25 mm/s	Yes	Yes
Selected Channels 10 min. + 25 mm/s	Yes	Yes
Event Table	Yes	Yes
Event Histogram	Yes	Yes
Heart Rate and ST Diagrams	Yes	Yes
HR diagram + Min/Max per Minute	Yes	Yes
RR Intervals	Yes	Yes
RR Delay	Yes	Yes
RR Histograms	Yes	Yes
RR Interval Spectra	Yes	Yes
Pacemaker Event Histogram	Yes	Yes
Pacemaker Function Analysis	Yes	Yes
Report	Yes	Yes
Print to File (PDF)	Yes	Yes
Save as Default Option	Yes	Yes

Editing & Reviewing Options	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and appearance of those options may vary.		
Scroll through all Beats in a Morphology Bin	Yes	Yes
Edit all Beat Labels in a Morphology Bin	Yes	Yes
Scroll through ECG and Edit Single Beat Labels	Yes	Yes
Scroll through Events of the Same Type	Yes	Yes
Edit Event Marker	Yes	Yes
View Patient Event Markers	Yes	Yes
Jump from any Statistics Diagram to the corresponding ECG	Yes	Yes
Jump from ECG Overview to the corresponding ECG	Yes	Yes
Select Time Interval for Time Domain RR Parameters	Yes	Yes
Edit Report	Yes	Yes

Miscellaneous	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
RZ153+ Digital Recorder Supported (K022540)	Yes	Yes
CardioMem® CM 3000 (SMA) Supported	Yes	Yes
CardioMem® CM 3000-12 Supported (K051686)	Yes	Yes
CardioMem® CM 3000-12BT Supported	No	Yes Bluetooth functionality only with Microsoft Windows XP (SP2)
CD Installation Medium	Yes	Yes

Standards Comparison

Standard	Legally marketed device CardioDay® Version 1.9.5 (K051471)	New / Modified Device CardioDay® Version 2.0
21 CFR 820 (FDA cGMP Good Manufacturing Practice)	Yes	Yes
ISO 9001:2000 / ISO 13485:2003 Quality Management Systems	Yes	Yes
IEC 60601-1-4 + A1 Programmable Electrical Medical Systems	Yes	Yes
ANSI/AAMI EC38 Ambulatory Electrocardiographs	Yes	Yes
IEC 60601-2-47 Particular Requirements for the Safety, including Essential Performance, of Ambulatory Electrocardiographic Systems	Yes	Yes
ISO 14971 +A1 Application of the Risk Management to Medical Devices	Yes	Yes
EN 980 Graphic Symbols for the Marking of Medical Devices	Yes	Yes
EN 1041 Supply of Information by the Manufacturer of a Medical Device	Yes	Yes
ISO 15223 + AMD1 + AMD2 Symbols to be Used with Medical Devices	Yes	Yes

Intended use:

CardioDay® is a software package that allows a trained physician or health care professional knowledgeable in Holter ECG interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording using a digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports.

This device is available only upon the order of a physician or other licensed medical professional and not intended for any ambulatory or home applications.

United States federal law restricts CardioDay® to sale by or on the order of a physician.

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Non-Clinical Testing:

Verification and validation test plans were completed in accordance with getemed AG procedures and GMP guidelines. A Hazard Analysis was completed and hazards were resolved as appropriate.

The CardioDay® software complies to the following standards:
- IEC 60601-1-4,
- IEC 60601-2-47,
- IEC 60601-2-51 (Part 50.101.2),
- ANSI/AAMI EC 38,
- ISO 14971,
- EN 980,
- ISO 15223,
- EN 1041

Also the following FDA-Guidelines were met:
- "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*",
- "*General Principles of Software Validation*".

All system specifications were met and testing performed to demonstrate substantial equivalence.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence of safety and effectiveness.

Conclusion:

The CardioDay® evaluation software is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2007

Getemed Medizin
c/o Mr. Bert Schadow
Regulatory Affairs Manager
14514 Teltow
Germany

Re: K070280
Trade Name: CardioDay
Regulation Number: 21 CFR 870.1425
Regulation Name: Computer, Diagnostic, Programmable
Regulatory Class: Class II
Product Code: DQK
Dated: January 3, 2007
Received: January 29, 2007

Dear Mr. Schadow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

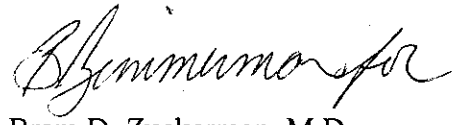
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070280
Exhibit 1

getemed
Medizin- und Informationstechnik AG

Indications for Use

510(k) Number (if known):

Device Name: CardioDay®

Indications For Use:

CardioDay® is a Holter software which is indicated for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality such as patients who have recently received pacemakers.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070280